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ORAL ARGUMENT NOT YET SCHEDULED

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

MEDICAL WASTE INSTITUTE and
ENERGY RECOVERY COUNCIL,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY,

Respondent.

No. 09-1297

Petition for Review of Final Administrative Action
of The United States Environmental Protection Agency

**FINAL BRIEF OF RESPONDENT
ENVIRONMENTAL PROTECTION AGENCY**

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), counsel for Respondent United States Environmental Protection Agency (“EPA”) acknowledges that Petitioner’s Brief correctly sets out the parties, rulings and related cases. References to the Ruling at issue appear in the brief for the Petitioner.

CORPRATE DISCLOUSRE STATEMENT

Respondent EPA is a governmental entity for which a corporate disclosure statement is not required.

So certified this 14th day of September, 2010, by

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GLOSSARY

CAA	Clean Air Act, 42 U.S.C. §§ 7401-7671q
Dkt.	Docket
EPA	United States Environmental Protection Agency
HAPs	Hazardous air pollutants
HMIWI	Hospital/Medical/Infectious Waste Incinerators
JA	Joint Appendix
MACT	Maximum achievable control technology
SSM	Start-up, shut-down and malfunction
<u>Key Rulemakings:</u>	
1997 Regulation	62 Fed. Reg. 48,348 (Sept. 15, 1977)
Proposed Rule	72 Fed. Reg. 5510 (Feb. 6, 2007)
Re-proposal	73 Fed. Reg. 72,962 (Dec. 1, 2008)
Challenged Regulation	74 Fed. Reg. 51,368 (Oct. 6, 2009)

ORAL ARGUMENT NOT YET SCHEDULED**JURISDICTIONAL STATEMENT**

Petitioners Medical Waste Institute, et al., challenge the United States Environmental Protection Agency's ("EPA's") promulgation of pollutant emissions standards for Hospital/Medical/Infectious Waste Incinerators ("HMIWI" or "medical incinerators"), set forth in EPA's rulemaking entitled "Standards of Performance for New Stationary Sources and Emissions Guidelines for Existing Sources: Hospital/Medical/Infectious Waste Incinerators," 74 Fed. Reg. 51,368 (Oct. 6, 2009) (the "Challenged Regulation").

This Court lacks jurisdiction to address the arguments set forth in three of the four issues raised by Petitioners, including: Issues 2 and 3 (Pet. Br. Part III), because the pollutant-by-pollutant approach that Petitioners challenge was promulgated by EPA in 1997 and was not revisited here, thereby rendering Petitioners' claims barred by the sixty-day filing deadline in 42 U.S.C. §7607(b)(1); and Issue 4 (Pet. Br. Parts IV-VI), because Petitioners failed to raise objections to EPA's elimination of the exemption for start-up, shut-down or malfunctions through an administrative request for reconsideration, as required under 42 U.S.C. §7607(d)(7)(B).

STATEMENT OF ISSUES

Section 129 of the Clean Air Act (“CAA”), 42 U.S.C. § 7429, requires EPA to promulgate emissions standards for solid waste incineration units for nine specific pollutants (and opacity, as appropriate), and to base those standards on the emissions limitations *actually achieved* by the *best-performing* units covered by the regulation. Petitioners’ objections to the Challenged Regulation, which was issued pursuant to this statutory requirement, raise the following issues:

1. Did EPA act rationally in promulgating emissions standards for medical incinerators based upon data reflecting emissions limitations *actually achieved* by covered entities, rather than on surrogate state regulations and permits that this Court already determined, in this *specific* case, formed an irrational basis for estimating the emission limitations *actually achieved* by medical incinerators?
2. Did EPA act rationally in promulgating emissions standards based on data reflecting emissions limitations actually achieved by the best performing units for *each* of the pollutants covered by CAA § 129, rather than on the aggregate emission limitations of the nine covered pollutants that a single unit could achieve?
3. Did EPA act rationally in eliminating an exemption (which this Court recently declared to be illegal in a closely related context) that allowed medical incinerators to potentially exceed emissions standards during start-up, shut-down

and malfunctions (“SSM”), because that exemption proved to be virtually useless for medical incinerators?

4. Does this Court have jurisdiction to address Petitioners’ claims with regard to the “pollutant-by-pollutant” and “SSM exemption” issues described in paragraphs 2 and 3 above?

STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in the Addendum to Petitioners’ brief.

STATEMENT OF THE CASE

Section 129 of the Clean Air Act, 42 U.S.C. §7429, requires EPA to promulgate emissions standards for new and existing medical incinerators for nine specified pollutants and, where appropriate, for opacity. These standards, which are based, in part, on implementation of “maximum achievable control technology” and hence are commonly referred to as “MACT” standards, must reflect the maximum degree of reduction in emissions of the covered pollutants.

Specifically, EPA must establish MACT standards that reflect a minimum required level of emissions reduction, otherwise termed a “MACT floor,” which by statute *must* be based on the emissions limitations (also referred to as “emissions levels” in relevant court decisions) that the best performing sources have *actually achieved* in practice. EPA also considers whether to promulgate MACT standards

reflecting stricter “beyond-the-floor” emissions limitations, after considering factors such as the cost of emission controls. 42 U.S.C. §7429(a). Although EPA conducted a beyond-the-floor analysis for medical incinerators, the Challenged Regulation did not ultimately establish or reset any beyond-the-floor emissions standards. Accordingly, this case involves solely a challenge to EPA’s resetting of the MACT floors for medical incinerators.

Pursuant to CAA §129, in 1997 EPA established emission standards for both new and existing medical incinerators. 62 Fed. Reg. 48,348 (Sept. 15, 1997). Because at that time EPA lacked sufficient data evidencing the emissions limitations actually achieved by operating medical incinerators, EPA based the MACT floors for medical incinerators on a surrogate. Specifically, EPA based the emissions standards for each of the covered pollutants on the emissions limitations EPA believed would be achieved if medical incinerators complied with regulations and permits issued by state authorities, supplementing this information where necessary with emissions levels from sources that assumed the *absence* of pollution control measures (the “state regulatory surrogate”).

In 1999, this Court remanded the 1997 emissions standards. Sierra Club v. EPA, 167 F.3d 658 (D.C. Cir. 1999) (“Sierra Club-HMIWI”). The Court found that although EPA was not generally precluded from using a state regulatory surrogate where actual emissions data did not exist, the record in this instance

lacked evidence establishing that the chosen surrogate reasonably approximated emissions limitations actually being achieved by medical incinerators. While allowing EPA an opportunity to more fully support its logic on remand, the Court found EPA's use of the state regulatory surrogate as applied to medical incinerators to be "hopelessly irrational." Id. at 664.

EPA determined on remand that it could not continue to justify the use of the state regulatory surrogate as the basis for formulating emission standards for medical incinerators. Indeed, EPA found that intervening decisions from this Court addressing the establishment of MACT emissions standards made it clear that continued use of the state regulatory surrogate as applied to medical incinerators would be improper. Accordingly, in response to this Court's remand, EPA issued the Challenged Regulation, which reset the MACT floors, this time basing them on data obtained from sources since 1997 reflecting the actual emission limitations achieved by existing medical incinerators. Consequently, the emission standards being challenged by Petitioners are based on precisely what CAA §129 requires: the emission limitations *actually achieved* by operating medical incinerators for each of the nine designated pollutants.

STATEMENT OF THE FACTS

A. Statutory Background

Section 129 of the Clean Air Act, 42 U.S.C. §7429, requires EPA to set New Source Performance Standards (“Standards”) and Emissions Guidelines (“Guidelines”) for all solid waste incineration units for nine enumerated pollutants. Those Standards and Guidelines (referred to generically as “standards”) are established pursuant to both CAA §129, which applies solely to solid waste combustion units, and CAA §111, which applies more generally to new and modified stationary sources. 42 U.S.C. §7429(a).¹

EPA’s MACT standards “shall reflect the maximum degree of reduction in emissions of [the specified] air pollutants [listed in subsection (a)(4)] that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is *achievable* for new or existing units....” 42 U.S.C. §7429(a)(2) (emphasis added). Emissions of pollutants can be reduced through a

¹ “Standards” apply to new sources, are implemented through EPA’s regulations, and become effective six months following promulgation. “Guidelines” apply to existing sources, are implemented through State plans, and are effective within the earlier of three years of EPA’s approval of a State plan or five years of the promulgation of the Guidelines. 42 U.S.C. §7429(a),(b),(f); Sierra Club-HMIWI, 167 F.3d at 660 n.1. Because the statute and relevant case law refer to both Standards and Guidelines under the single label of “standards,” EPA will do so here. Similarly, CAA §129 applies the standards to “units,” while CAA §111 applies the standards to “sources.” Because the cases generally use the terms interchangeably, EPA will do the same here.

variety of mechanisms. “Control technologies,” such as wet or dry scrubbers, reduce emissions through add-on control devices that work at the “stack,” where pollutants are emitted. Pollutants from incinerators also are controlled through “combustion control” (the proper design, construction and operation of an incinerator) and “waste segregation” (the separation of various forms of waste prior to incineration). Each of these three practices helps, respectively, to reduce emissions of some, but not all, of the covered pollutants. 74 Fed. Reg. at 51,369.

Although MACT standards are to be based on these methods and technologies potentially available to remove or destroy the covered pollutants, 42 U.S.C. §7429(a)(3), EPA does not direct a source to install particular types of control technologies, combustion controls, or methodologies for removing waste. Instead, EPA must promulgate the standards as numeric emission limits, 42 U.S.C. §7429(a)(4), leaving each source to decide how best to achieve those standards.

In addition to the general standards outlined above, EPA’s MACT standards must, *at a minimum*, reflect the emission limitations that EPA identifies as the “floor.” 42 U.S.C. §7429(a)(2); 74 Fed. Reg. at 51,370/1. Specifically, floors for *new* units must reflect emissions reductions that are “*achieved in practice* by the *best controlled* similar unit, as determined by the Administrator.” 42 U.S.C. §7429(a)(2) (emphasis added). While the floors for *existing* units may be less

stringent, they “shall not be less stringent than the average emissions limitation achieved by the best performing 12 percent of units in the category....” Id.

Accordingly, while EPA *may* issue MACT standards that reflect more stringent, *achievable* “beyond-the-floor” emissions limitations, so long as costs and other factors are adequately considered, EPA *must*, at a minimum, establish MACT floors. Those floors are to be determined without consideration of costs or other factors and are to be based on the emissions limitations *actually achieved* by the single best performing source (for new sources) or the average of the best performing 12% of sources (for existing sources). Id. See also Cement Kiln Recycling Coal. v. EPA, 255 F.3d 855, 861-62 (D.C. Cir. 2001).

The setting of the MACT floors and any potential beyond-the-floor standards is the first step of the regulatory process. In later and separate steps EPA revisits those standards to determine whether they need to be tightened. Sierra Club v. EPA, 353 F.3d 976, 980 (D.C. Cir. 2004) (“Sierra Club-Copper”). Five years following promulgation of MACT standards under CAA §129(a)(2), EPA “shall review, and in accordance with this section and section 7411 of this title, revise such standards and requirements.” 42 U.S.C. §7429(a)(5) (the “five-year review provision”). See also 42 U.S.C. §7411(b)(1)(B). Additionally, CAA §129(h)(3) provides that EPA is to promulgate “residual risk” standards under section 112(f), 42 U.S.C. §7412(f), if EPA determines that such promulgation is

required in order to provide an ample margin of safety to protect public health, or, after considering costs, safety, and other factors, to prevent an adverse environmental effect. 42 U.S.C. §§7429(h)(3), 7412(f)(2)(A) (“residual risk standard”); NRDC v. EPA, 529 F.3d 1077, 1080 (D.C. Cir. 2008).

B. The 1997 Regulation

On September 15, 1997, EPA issued its first MACT standards for medical incinerators. 62 Fed. Reg. 48,348. Although the MACT floors were expressly required by CAA §129(a)(2) to be based on the emissions limitations actually achieved by the best-performing medical incinerators, in 1997 there existed a lack of data reflecting the emissions limitations achieved by those units. See, e.g., 72 Fed. Reg. 5510, 5513 (Feb. 6, 2007) (EPA had data from 7 of the estimated 3,700 medical incinerators operating in 1995). Accordingly, EPA used a surrogate to attempt to estimate the actual emissions limitations of the best-performing existing units. Specifically, EPA based the MACT floor emission limitations on the emissions it projected medical incinerators would achieve if they complied with the panoply of state regulations and permit requirements. 62 Fed. Reg. at 48,352.

Even with this surrogate, however, there were an insufficient number of medical incinerators covered by state regulations and permits to generate a population of units large enough to project the emission limitations of the best-performing 12% of units, which is required to set the floor for existing units. 42

U.S.C. §7429(a)(2). Consequently, EPA supplemented its regulatory projections with information from tests performed on a limited number of medical incinerators that utilized no pollution controls. 62 Fed. Reg. at 48,352. In other words, EPA based its projections of emission limitations achieved by the *best*-performing 12% of covered units, in part on units that were assumed to employ no pollution control technologies whatsoever.

Utilizing the state regulatory surrogate (as supplemented with data from uncontrolled units), EPA set MACT floors for both new and existing units for each of the nine covered pollutants. A number of commenters asserted that EPA should not set MACT floors on a pollutant-by-pollutant basis but instead should base the MACT floors on the emission limitations of each pollutant that can be achieved by a single unit (the “single-unit” approach). *Id.* at 48,363. EPA rejected this suggestion, finding that CAA §129 is most reasonably interpreted to require EPA to “set the MACT floor pollutant-by-pollutant.” *Id.* at 48,364/1.

C. This Court’s Decision in Sierra Club-HMIWI

In Sierra Club-HMIWI, Sierra Club challenged the 1997 Regulation, “complaining principally that EPA failed to comply with the specifications of §7429(a)(2) for the floors.” 167 F.3d at 660. Although the Court rejected Sierra Club’s statutory construction challenge, it “conclude[d] that there are serious

doubts about the reasonableness of EPA's treatment of the floor requirements....”

Id.

With regard to *existing* sources, the Court explained that the 1997 Regulation set out 27 floor emission standards; one for each of the nine covered pollutants in each of the three categories of sources, small, medium and large. Id. As the Court outlined, EPA's use of the state regulatory surrogate required the Agency to: (a) opine as to the equipment or methods medical incinerators would utilize to comply with state permit requirements; and (b) then estimate the emissions limitations that those incinerators would achieve using such methods and equipment. The Court then explained that for 17 of the 27 floor determinations, the population of covered sources subject to state regulatory requirements was less than the 12% of sources necessary to determine emission limitations of the best-performing 12% of covered sources. Id. at 661. “So for these 17, EPA supplemented the [state] regulatory data with ‘uncontrolled’ data – data from its test program recording the performance of incinerators with no pollution controls.” Id.

Noting that EPA had actual emissions data for only about 1% of the medical incinerators in existence, id. at 663, the Court upheld the right of EPA, as a general matter, to use a surrogate, such as state regulatory permits, to estimate actually achieved emissions limitations. The Court found, however, that in *this*

case, EPA had failed to justify how using its combination of estimations of emissions limitations based on compliance with state regulations and permits with emissions values from sources lacking emission control technology, reasonably approximated the MACT floor, i.e., the emissions limitations actually being achieved by the best performing sources. Id.

The Court provided several examples to “illustrate the deficiencies in EPA’s explanation”:

First, EPA has said nothing about the possibility that MWIs might be substantially overachieving the [state] permit limits. If this were the case, the permit limits would be of little value in estimating the top 12 percent of MWIs’ performance. Data in the record suggest that the regulatory limits are in fact much higher than the emissions that units achieve in practice.

Id. Indeed, the Court found that for about half of the 27 MACT floor standards set by EPA, the floor, i.e., the emissions limitations that EPA *assumed* were reached by the average of the top performing 12% of sources, was actually higher than the limitations achieved by sources that used no pollution controls whatsoever. Id. The Court concluded, “[e]ven under the most deferential standard, it is difficult to accept a method under which the emissions of the best-performing 12% of units are hypothesized to pollute nearly twice as badly as the worst of test units that lacked any emissions controls.” Id. at 664.

Accordingly, the Court found that the manner in which EPA applied the state regulatory surrogate, as well as a number of assumptions EPA used in that

application, were irrational. See, e.g. id. at 664: “It is difficult to see the rationality in using ‘uncontrolled’ data for the units that were not subject to regulatory requirements;” “[D]ata on which EPA relied strongly suggest that it was irrational to suppose that any of the incinerators in the top 12% were uncontrolled...;” “[I]t is difficult to see how it was rational to include any uncontrolled units in the top 12 percent...;” “With these numbers, EPA’s method looks hopelessly irrational.”

EPA fared no better with regard to the floors it set for *new* sources, which are to be based on the emission limitations achieved by the single best-performing source for each pollutant. Lacking actual emissions data reflecting the emissions limitations achieved by the best-controlled similar source, in this case “EPA examined each subcategory and identified the most effective technology in use by an incinerator in that subcategory.” Id. at 664. To determine the emissions limitations that were achieved utilizing that technology, EPA relied on data from its testing program and identified the *highest* level of emissions recorded in any test, and then increased that value by 10%. Id. at 665. In this instance, the Court questioned how the highest emissions levels plus 10% (i.e., the worst performing source using a specific technology, adjusted upward by 10%), is a reasonable surrogate for a standard that must be based on the “best controlled similar unit.” Id. (quoting 42 U.S.C. §7429(a)(2)).

Based on these findings, the Court remanded EPA's MACT floor determinations with regard to both new and existing sources. Id. at 666. The Court remanded the Regulation without vacatur because Petitioner "Sierra Club has expressly requested that we leave the current regulations in place during remand, rather than eliminate any federal control at all." Id. at 664. Although obviously skeptical, the Court suggested that on remand it may be "possible that EPA may be able to explain" an adequate basis for its methodology in setting the floors. Id. No party to the 1999 case, including industry intervenors, challenged EPA's conclusion in the 1997 Regulation that whatever surrogate standard, data or other basis is used to *quantify* the MACT floors, floor emission standards should be determined on a pollutant-by-pollutant basis.

D. Intervening Case Law – 2000 to 2008

Following the 1999 Sierra Club-HMIWI decision, the D.C. Circuit issued a number of decisions of which EPA took notice in issuing the Challenged Regulation. Most of these cases dealt with CAA §112, 42 U.S.C. §7412, which requires EPA to set MACT standards for sources that emit any of the more than one hundred hazardous air pollutants ("HAPs") covered by that provision. Although the provisions of CAA §112 differ somewhat from those of CAA §129, the provisions relevant to this case – those regarding establishment of MACT floors for new and existing sources – are virtually identical. Nat'l Lime Ass'n v.

EPA, 233 F.3d 625, 631 (D.C. Cir. 2000) (noting that CAA §129 establishes “emissions requirements virtually identical to section [112’s]”). See also Cement Kiln, 255 F.3d at 861-62, 871; Intervenor/Amici Br. 19.

In Cement Kiln, the Court found that where factors other than control technologies (e.g., waste segregation) have more than a negligible effect on emissions, those factors *must* be considered in setting the MACT floors. 255 F.3d at 866. As the Court explained: “[I]f factors other than MACT technology do indeed influence a source’s performance, it is not sufficient that EPA considered sources using only ... MACT controls. Id. at 864-65. See also Nat’l Lime, 233 F.3d at 633 (finding that the same argument “may well have merit” but disregarding it because Petitioner had failed to raise it in its opening brief).

In Sierra Club v. EPA, 479 F.3d 875 (D.C. Cir. 2007) (“Sierra Club-Brick”), EPA had refused to consider the effects of non-control factors in setting MACT floors because it lacked evidence that entities deliberately implemented those techniques to reduce emissions. The Court, however, made it clear that intent was irrelevant and that the failure to consider emission-reducing, non-technology factors in setting emissions standards was impermissible:

“[T]he Clean Air Act requires the EPA to set MACT floors based upon the average emission limitation[s] achieved;’ it nowhere suggests that this achievement must be the product of a specific intent.” [Nat’l Lime], 233 F.3d at 640 (citation omitted). EPA’s decision to base floors exclusively on technology even though non-technology factors affect emission levels thus violates the Act.

Id. at 883.

E. The 2009 Challenged Regulation

1. The Original Proposed Rule

On February 6, 2007 (one month *before* this Court issued its decision in Sierra Club-Brick), EPA issued a proposed rule in response to the Court's remand in Sierra Club-HMIWI. 72 Fed. Reg. 5510 (the "Proposed Rule"). In considering the concerns raised by the Court, EPA determined that, in fact, its use of the state regulatory surrogate as it had been applied in the 1997 Regulation could not be justified. See, e.g., 72 Fed. Reg. at 5529:

After reviewing the 1997 HMIWI record in the context of the Court's opinion, EPA agrees that, in determining the MACT floor, the Agency should not have used regulatory limits that reflected higher emission levels (and that did not appear to be related to any air pollution controls) than those corresponding to EPA's combustion-controlled emission estimates. Furthermore, as we examined the 1997 record and our estimates of the performance of HMIWI where we had some indication that add-on controls may have been used, we determined that we should not have used combustion-controlled [i.e., uncontrolled] emission estimates in the floor calculations to represent the performance of those sources.

See also id. at 5528 ("EPA agrees that a regulatory limit does not reflect 'actual performance' when that limit is higher than the level attributed to the worst

reasonably foreseeable performance of an uncontrolled (i.e., combustion controlled) source.”).²

To address these issues, EPA proposed resetting the MACT floors for both new and existing sources. While these reset floors would be “in many cases [] more stringent than the limits promulgated in 1997,” they were, nevertheless, still based on the limited information available in 1997. *Id.* at 5529. Essentially, the Proposed Rule continued to utilize the state regulatory surrogate, with some modifications. 73 Fed. Reg. 72,962, 72,969 (Dec. 1, 2008).

Separate and distinct from the revised MACT floors proposed in response to the Court’s remand, EPA conducted its required five-year review, under which EPA may, if appropriate, “revise such standards and requirements.” 42 U.S.C. §7429(a)(5). As EPA explained, “[i]n performing this 5-year review, we have not recalculated new MACT floors, but have proposed to revise the emissions limits to reflect the actual performance of the MACT technologies.” 72 Fed. Reg. at 5533. Noting that the data then available revealed emissions reductions “superior to what we expected under the 1997 limits for many of the pollutants,” EPA proposed revising many of the standards, explaining:

² For the purposes of its discussion, EPA equated “combustion controls” to what the Court in *Sierra Club-HMIWI* termed as “no controls,” because its limited 1997 test data did at least attempt to factor in combustion controls. 73 Fed. Reg. at 72,966/2.

EPA believes that the proposed emission limits more accurately reflect actual real-world HMIWI MACT performance than what we had estimated in 1997 and what we re-estimated [for the revised MACT floors] based on the 1997 record in response to the Court's remand (discussed previously in this preamble). We believe that it is necessary, as well as appropriate, to update the 1997 promulgated standards based on the actual performance of MACT technologies in situations where compliance test data indicate that the technologies achieve better performance levels than those we previously estimated based on the information available at the time of promulgation.

Id. at 5533-34. Thus, while EPA proposed continuing to base the MACT floors on 1997 information and the state regulatory surrogate as further modified, it also proposed strengthening the MACT standards based on more recent emissions data, pursuant to its authority to conduct a five-year review.

2. The Re-Proposed Rule

On December 1, 2008, EPA issued a new proposed rule, the "Re-proposal." 73 Fed. Reg. 72,962. As EPA explained, it was necessary to issue a Re-proposal because the 2007 Proposed Rule could no longer be supported: "Upon reassessment of the regulatory limits and minimal emissions test data in the 1997 record, however, it is uncertain how well the regulatory limits represented the performance of each HMIWI." Id. at 72,970. Indeed, a comparison of state regulatory limits with the limited emissions data available in 1997 pointed to the conclusion that the state regulatory surrogate, even as modified in the Proposed Rule, did not reflect the emissions limitations actually achieved in 1997. Id. at 72,979; 74 Fed. Reg. at 51,378/2.

Additionally, the cases outlined above, including the Sierra Club-Brick case decided after publication of the Proposed Rule, made it clear that EPA could not base the MACT floors on projections of emissions from use of control technology alone, so long as there was evidence that non-control technology factors act to reduce actual emissions of medical incinerators. 73 Fed. Reg. at 72,970. EPA explained: “[B]ased on recently obtained information, we now understand that factors other than the controls (e.g., waste mix and combustion conditions) affect HMIWI performance, and those emission reduction strategies must be accounted for in MACT floor determinations.” Id. at 72,975. See also 74 Fed. Reg. at 51,377-79.

Accordingly, the Re-proposal proposed establishing MACT floors based on actual emissions data generated after 1997, not on the state regulatory surrogate:

Given the uncertainty regarding whether the regulatory limits that specific HMIWI were subject to at the time of promulgation provided a reasonable estimate of emissions limitations achieved by those HMIWI, the inability to gather additional information regarding non-operational units (approximately 98% shut down or obtained exemptions), and the fact that we now have some actual emissions data from the HMIWI remaining in operation, we believe the best course of action is to re-propose a response to the remand based on data from the 57 currently operating HMIWI. This data is the most reliable we have obtained that reflects the emissions levels achieved in practice by the best performing HMIWI.

73 Fed. Reg. at 72,970.

3. The 2009 Final (Challenged) Regulation

In EPA's final response to this Court's remand in Sierra Club-HMIWI, the Challenged Regulation reset the MACT floors for new and existing medical incinerators based on the actual emissions data EPA had obtained for post-2002 operations. 74 Fed. Reg. at 51,378-79. Although the emissions standards originally proposed in the 2007 Proposed Rule relied upon both reset MACT floors *and* the five-year review required under CAA §129(a)(5) to set new standards, the final Challenged Regulation set no new emissions standards pursuant to the five-year review provision. 74 Fed. Reg. at 51,372/1. The Challenged Regulation did, nevertheless, discharge EPA's duty to conduct a five-year review. Id. at 51,372, 51,379.

EPA did not conduct a residual risk review with regard to medical incinerators under CAA §129(h)(3) as part of the Challenged Regulation nor did the Challenged Regulation include any new or reset beyond-the-floor limitations. Accordingly, the Challenged Regulation did not establish any of the more stringent emissions standards possible under the beyond-the-floor, residual risk, or five-year review provisions. Instead, the revised standards are based solely on criteria for establishing MACT floors, promulgated pursuant to EPA's mandate to establish *minimum* emissions standards under 42 U.S.C. §7429(a)(2). 74 Fed. Reg. at 51,368.

The 1997 Standards also had contained a limited exception from the requirement to continuously comply with emissions standards, exempting emissions occurring during periods of start-up, shut-down and malfunction (“SSM”), so long as no hospital or infectious waste was charged to the unit during the SSM periods. Id. at 51,375/2-3. In another MACT case decided after the Proposed Rule was published, Sierra Club v. EPA, 551 F.3d 1019 (D.C. Cir. 2008) (“Sierra Club-SSM”), cert. denied, 130 S.Ct. 1735 (2010), this Court vacated a similar SSM exemption for pollutants covered by CAA §112, based on its finding that the SSM exemption violates the CAA’s requirements that emissions standards must be continuously met. Accordingly, EPA explained in the Challenged Regulation that continued application of the SSM exemption for MACT standards under CAA §129 for medical incinerators is legally questionable. 74 Fed. Reg. at 51,394/2. While taking note of this decision, EPA separately concluded that the SSM exemption should be eliminated because, given the nature of medical incinerator operations, the exemption “is of virtually no utility to HMIWI.” Id. at 51,394/3.

SUMMARY OF ARGUMENT

Notwithstanding references by Petitioners to the various mechanisms EPA may use to establish or revise MACT standards, their challenge in this case has nothing to do with setting beyond-the-floor standards or how or on what basis EPA

may establish emissions standards pursuant to its 5-year review or residual risk analyses. The *only* issues remanded in Sierra Club-HMIWI, and the *only* regulatory action being challenged by Petitioners, is EPA's establishment of revised MACT *floors* for new and existing medical incinerators.

Whatever can be said about CAA §129, EPA's obligation under that provision with regard to setting the MACT floors is unwaveringly clear. EPA is required by section 129(a)(2) to establish the numeric MACT floors for each of the pollutants listed in section 129(a)(4) based on the *emissions limitations actually achieved in practice* by the *best-performing* source or the average of the best performing 12% of sources, depending on whether EPA is setting the floors for new or existing sources. Thus, EPA's task is, in the end, straightforward: analyze the emissions data of the best-performing sources and set the numeric MACT floors for each pollutant based on the emissions limitations actually being achieved by those sources.

Petitioners do *not* assert that EPA's revised MACT floor standards fail to reflect the actual emissions of section 129(a)(4)'s nine specified pollutants from the best-performing medical incinerators. Instead, Petitioners first argue that EPA is foreclosed from responding to this Court's remand by re-setting the MACT floors based on actual emissions data now available to the Agency. They argue that EPA must instead continue to rely on information – or more accurately, the lack thereof

– from 1997, thereby consigning EPA to rely on unsupportable surrogates to substitute for existing data reflecting actual emissions limitations achieved.

Alternatively, Petitioners assert that even if it is permissible for EPA to rely on contemporaneous emissions data, EPA must abandon its longstanding pollutant-by-pollutant approach to setting MACT standards, i.e., ignore the emissions limitations actually achieved by operating units for *each* covered pollutant, and instead re-establish the standards based on the aggregate emissions limitations of *all* covered pollutants that a single unit emits.

Petitioners' effort to force EPA to maintain discredited emissions floors, even in the face of hard data revealing such floors to be well above the actual emissions limitations achieved in 1997, is wholly unsupportable. Petitioners simply advocate that EPA be compelled to reapply the state regulatory surrogate, offering no explanation as to how that can be accomplished in a manner consistent with this Court's description of the infirmities inherent in that surrogate as applied to medical incinerators *or* with this Court's other post-1997 MACT rulings. Indeed, by their own admission, Petitioners' arguments would require EPA to establish MACT floors based on the emissions limitations achieved by the *worst*-performing sources, at least for some of the covered pollutants: a result that this Court has repeatedly admonished is inconsistent with statutory requirements.

Petitioners' separate argument that EPA must set the individual pollutant MACT floors based on what a single unit could achieve for *all* covered pollutants, rather than on what actual units have in fact achieved for *each* of the nine covered pollutants, is barred by the 60-day filing requirement in 42 U.S.C. §7607(b)(1). EPA established its pollutant-by-pollutant approach to setting all MACT standards (floor and beyond-the-floor) in 1997, and did not re-open or revisit that issue in the Challenged Regulation. Even if the Court were, however, to determine that it possessed jurisdiction to address this issue, it must uphold EPA's application of the pollutant-by-pollutant approach, because it most certainly represents a rational interpretation of EPA's obligations under CAA §129.

Finally, Petitioners' challenge to EPA's removal of the SSM exemption for medical incinerators also is barred, since it was not first raised to EPA through an administrative petition for reconsideration as required by CAA §307(d). Even if it had been properly raised, however, EPA's determination that this now legally-questionable exemption should be eliminated for record-based reasons, namely because it is virtually useless to medical incinerators, is both supported by the record and eminently reasonable.

ARGUMENT

I. STANDARD OF REVIEW

EPA's action in promulgating the Challenged Regulation can be overturned only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or in excess of EPA's "statutory jurisdiction, authority, or limitations." 42 U.S.C. §7607(d)(9). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). See also FCC v. Fox Television Stations, Inc., 129 S. Ct. 1800, 1810 (2009).

Because Petitioners assert that EPA misinterpreted the CAA, the standards announced in Chevron U.S.A. Inc. v. NRDC, Inc., 467 U.S. 837 (1984), apply. While a court must apply the language of the statute where it reflects "the unambiguously expressed intent of Congress," if the statute is "silent or ambiguous with respect to the specific issue," the court must defer to the agency's interpretation so long as it is "based on a permissible construction of the statute." Id. at 842-43. Particular deference is to be given to an agency's interpretation of a statute it administers when the statute is complex and within the agency's expertise. United States v. Mead Corp., 533 U.S. 218, 227-31 (2001). The CAA is

precisely this type of statute. NRDC v. EPA, 571 F.3d 1245, 1251 (D.C. Cir. 2009).

When an agency's action relies on scientific or technical information touching upon the agency's area of expertise, a reviewing court applies "an extreme degree of deference." Huls Am. Inc. v. Browner, 83 F.3d 445, 452 (D.C. Cir. 1996). See also Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512, 519 (D.C. Cir. 2009). Thus, in this case the Court need only find "that EPA's understanding of this very 'complex statute' is a sufficiently rational one to preclude a court from substituting its judgment for that of EPA." Chemical Mfrs. Ass'n v. NRDC, Inc., 470 U.S. 116, 125 (1985).

II. EPA ACTED REASONABLY IN RESETTING THE MACT FLOOR STANDARDS BASED ON EXISTING DATA THAT REFLECTS ACTUAL EMISSIONS LIMITATIONS

Petitioners make a rather remarkable assertion: that on remand from this Court's decision questioning the rationality of EPA's use of the state regulatory surrogate to determine the emissions limitations actually achieved by the best-performing sources, EPA *must* ignore existing data of actual emission limitations achieved, and instead must continue to apply the 1997 state regulatory surrogate discredited by this Court. Petitioners offer: (a) no credible statutory interpretation compelling this result; (b) no case law supporting their argument; (c) no explanation of how EPA could continue to apply that surrogate in light of the

intervening decisions of this Court; and (d) no citation to *any* record evidence that might lead to the conclusion that continued use of the state regulatory surrogate is even arguably supportable, in light of the serious concerns identified by this Court.

Instead, Petitioners rely on labels such as “MACT-on-MACT” and wholly unsupportable supposition about the effect of the 1997 MACT floors on the medical incinerator “industry,” to assert that it is unfair for these entities to have to achieve emissions standards beyond those based on the discredited 1997 state regulatory surrogate. As outlined below, EPA did *not* revise the MACT floor standards based upon actions that incinerator operators took in response to the 1997 standards (so-called MACT-on-MACT). Moreover, it is not unfair in any sense of the word to require incinerator operators to comply, at last, with the standards Congress intended to be implemented under CAA §129. Finally, while EPA unfortunately did not have sufficient information to establish proper emissions standards from the outset, that does not alter the Agency’s obligation to establish those standards as required under the statute.

A. EPA Permissibly Reset the MACT Floor Standards Based on Actual, Contemporaneous Emissions Data

Petitioners assert that “MACT floors [are] to be set one time, when the standards are first promulgated,” and, therefore, any attempt to reset those floors violates CAA §129. Pet. Br. 15. Not surprisingly, Petitioners fail to cite a single case standing for the proposition that EPA is prohibited from revising the original

MACT floors, let alone after they have been remanded by the Court due to serious legal infirmities. Instead, Petitioners contend that because CAA §129 calls for EPA to initially set MACT floors, and also contains a provision requiring EPA to conduct five-year reviews of the MACT standards it sets, 42 U.S.C. §7429(a)(5), this evidences Congress' intent that once a MACT floor is set (even incorrectly or illegally), it can never be changed, except as part of the five-year review process. Pet. Br. 15-16.

There simply is nothing in CAA §129 or its legislative history that even suggests that EPA is prohibited from resetting emissions floors *except* as part of its five-year review conducted under CAA §129(a)(5). More importantly, there is no provision of section 129 that could possibly be construed to require EPA, *on remand*, to issue revised standards based on the same lack of credible data and information that the Court already has found lacking. Yet, this is precisely what Petitioners advocate.

Petitioners offer no alternative data from 1997. They make no argument that EPA overlooked data available in 1997 that could be used to reasonably approximate actual emissions limitations achieved. To the contrary, Petitioners acknowledge the lack of data available to EPA in 1997. Pet. Br. 22 (citing EPA's finding of a lack of data on waste segregation in 1997). Instead, Petitioners assert that this Court's decision in Sierra Club-HMIWI merely asked for an additional

explanation from EPA of how the state regulatory surrogate accurately reflects actual emissions achieved and that it “did not question the extent of the data in the 1997 database.” Pet. Br. 18. Petitioners argue that EPA must, therefore, continue to employ the state regulatory surrogate based on 1997 data in setting the MACT floor, even if that surrogate cannot reasonably be used to approximate actual emissions. This is not only a complete misreading of the Court’s opinion in Sierra Club-HMIWI, it misapprehends the authority and responsibilities of agency to address deficiencies in its rulemaking on remand from a Court of Appeals and to otherwise correct errors in its regulations.

1. EPA Had Full Authority to Reset the MACT Floors

While vacatur vitiates the challenged regulation, a remand does not, as Petitioners imply, imbue the regulation with everlasting validity. To the contrary, a remanded regulation can only be resurrected “after remedying the defects that vitiated the original action.” Action on Smoking & Health v. CAB, 713 F.2d 795, 798 (D.C. Cir. 1983) (quoting Williams v. Washington Met. Area Transit Comm’n, 415 F.2d 922, 939-40 (D.C. Cir. 1968)). Although a remand may, as here, provide an agency with a second opportunity to attempt to support its original regulation, it does not *validate* the regulation. Instead, it merely provides the agency with a new opportunity to consider whether it can support its original action on some alternative ground. See, e.g., County of Los Angeles v. Shalala, 192 F.3d. 1005,

1023 (D.C. Cir. 1999) (“While we have identified significant inconsistencies and gaps in the Secretary’s rationale..., bedrock principles of administrative law preclude us from declaring definitively that her decision was arbitrary and capricious without first affording her an opportunity to articulate, if possible, a better explanation.”); Checkosky v. SEC, 23 F.3d 452, 463 (D.C. Cir. 1994) (“This is but one of many instances where we have remanded to an agency for a better explanation before finally deciding that the agency’s action was arbitrary and capricious.”).

Moreover, an agency generally remains free to undo improperly promulgated or otherwise unsupportable rules, even in the absence of a remand. United Gas Improvement Co. v. Callery Props., Inc., 382 U.S. 223, 229 (1966) (“An agency, like a court, can undo what is wrongfully done by virtue of its order.”); Macktal v. Chao, 286 F.3d 822, 825-26 (5th Cir. 2002) (“[I]t is generally accepted that in the absence of a specific statutory limitation, an administrative agency has the inherent authority to reconsider its decisions.”). Agencies have particularly broad authority to revise their regulations to correct their errors. Last Best Beef, LLC v. Dudas, 506 F.3d 333, 340 (4th Cir. 2007); Friends of the Boundary Water Wilderness v. Bosworth, 437 F.3d 815, 823 (8th Cir. 2006), (“It is widely accepted that an agency may, on its own initiative, reconsider its interim or

even final decisions, regardless of whether the applicable statute and agency regulations expressly provide for such review.”) (citation omitted).

In reconsidering its regulation on remand, an agency cannot be forced to reinstate the original regulation, even if it *could* find ample support for it. As the Supreme Court has explained, a court cannot usurp the authority granted to an agency by Congress by directing that agency how – or even whether – to issue a new or revised regulation. INS v. Ventura, 537 U.S. 12, 16 (2002); Florida Power & Light Co. v. Lorian, 470 U.S. 729, 744 (1985); SEC v. Chenery Corp., 318 U.S. 80, 88 (1943); Trujillo v. General Elec. Co., 621 F.2d 1084, 1086 (10th Cir. 1980) (“The authority [of an agency] to reconsider [a prior-issued regulation] may result in some instances, as it did here, in a totally new and different determination....”).

Moreover, an agency may reconsider its methodologies and application of its statutory requirements and may even completely reverse course, regardless of whether a court has determined that its original regulation is flawed, so long as the agency explains its bases for doing so. Motor Vehicle Mfrs. Ass’n, 463 U.S. at 42; FCC v. Fox Television Stations, Inc., 129 S. Ct. at 1810; Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs., 545 U.S. 967, 981-82 (2005) (internal citation omitted):

“An initial agency interpretation is not instantly carved in stone. On the contrary, the agency ... must consider varying interpretations and the wisdom of its policy on a continuing basis,” Chevron, *supra* at 863-864 [], for example, in response to changed factual

circumstances, or a change in administrations. That is no doubt why in Chevron itself, this Court deferred to an agency interpretation that was a recent reversal of agency policy.

Not only is EPA's issuance of new or reset MACT floors permissible, it is precisely what this Court *expected* EPA to do given the circumstances presented. In Northeast Maryland Waste Disposal Authority v. EPA, 358 F.3d 936 (D.C. Cir. 2004), EPA promulgated regulations under CAA §129 for municipal waste combustors that mirror those issued for medical incinerators in 1997 under the identical provision. There, as here, EPA based the emissions standards on "emission limits contained in state permits." Id. at 953. There, as here, where there were too few units subject to state permits to assess the performance of the top 12% of sources, EPA estimated emission limitations from uncontrolled units. Id. There, as here, the Court found that MACT floors based on this state regulatory surrogate were unsupportable, citing the very same reasoning announced in Sierra Club-HMIWI:

As in Sierra Club[-HMIWI], EPA here stated only that it "believes" state permit limits reasonably reflect the actual performance of the best performing units without explaining why this is so. There is also evidence here that the MWCs, like the MWIs in Sierra Club[-HMIWI], "might be substantially overachieving the permit limits," that is, "the regulatory limits are in fact much higher than the emissions that units achieve in practice." 167 F.3d at 633.

358 F.3d at 954.

Consequently, the Court concluded: “We agree that EPA has not shown that the technology-based approach will achieve a reasonable estimate of the emission level achieved by the best performing MWC unit and, accordingly, remand to the Agency to establish MACT floors.... [W]e remand for new MACT floors....” *Id.* at 955 (emphasis added). See also *Cement Kiln*, 255 F.3d at 871-72 (remanding for EPA to set new floors, where EPA can choose whatever methodology it deems appropriate, even “abandon[ing] the MACT approach altogether.”). Thus, this Court has made clear that unless EPA both chooses to and can, in fact, support continued use of the state regulatory surrogate, EPA is to establish *new* MACT floors, and it is to do so in response to the Court’s remand and section 129(a)(2), i.e., it is not limited to resetting the standards only through its five-year or residual risk review procedures.

2. EPA’s Decision to Reset the MACT Floors Based on Contemporaneous Data Reflecting Actual Emissions was Reasonable

As this Court has frequently announced and as Petitioners concede, CAA §129 requires EPA to set the MACT floor based on emissions limitations *actually achieved* by the best-performing medical incinerators. Quite obviously, the best way to ascertain the actual emissions limitations achieved by the best-performing units is to use data reflecting the actual emissions of operating units. While the Court has acknowledged that EPA may use a surrogate when actual data are

unavailable, that surrogate must still result in a reasonable estimation of the actual emissions limitations being achieved by the best-performing sources. Northeast Maryland Waste Disposal Authority, 358 F.3d at 954 (“EPA must ‘demonstrate with substantial evidence – not mere assertions’ – that the chosen floors ‘represent “a reasonable estimate of the performance of the [best performing] units”’.” (quoting Cement Kiln, 255 F.3d at 866 and Sierra Club-HMIWI, 167 F.3d at 662); National Lime, 233 F.3d at 632 (“We agree that to comply with the statute, EPA’s method of setting emission floors must reasonably estimate the performance of the relevant best performing plants.”)).

In this case, the Court in Sierra Club-HMIWI did not tell EPA that the Agency just had to do a little tweaking to its surrogate or add a few sentences to more fully explain how the state regulatory surrogate resulted in a reasonable estimation of emissions limitations actually achieved by the best-performing sources. To the contrary, the Court found that EPA’s application of the state regulatory surrogate, based on the information and support EPA was able to muster, appeared “hopelessly irrational.” 167 F.3d at 664.

On remand, EPA determined that no matter how it attempted to reconsider the information available in 1997, the state regulatory surrogate could never reasonably approximate the emissions limitations actually achieved by the best-performing medical incinerators. First, in attempting to address the Court’s

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admonishment that EPA should not use test data from assumed-to-be uncontrolled sources to supplement state regulations in assessing the best emission limitations achieved, EPA found that there existed no other reasonable 1997 data that could be used to fill the gaps in the state regulatory surrogate, nor was it possible to generate or obtain such data. 74 Fed. Reg. at 51,378-79. Second, in reviewing the limited data of actual emissions that was available in 1997, it became evident that the state regulatory surrogate did not come close to approximating the emissions limitations actually achieved. Id. Finally, state regulations and permits did not reflect the use of actually employed waste segregation and other non-technology factors, which this Circuit has now firmly established *must* be considered in assessing actual emissions limitations of the best-performing sources. Id. Thus, EPA concluded that “it became impossible to fully address the Court’s concerns about the suitability of using regulatory limits and uncontrolled emissions values from the 1997 data set in rationally explaining the MACT floors for the 1997 rule.” 74 Fed. Reg. at 51,378.

Petitioners offer no data, evidence or even arguments to refute the first two conclusions of EPA set out above. As to the requirement that EPA include the effects of waste segregation and other non-control technology factors in setting the MACT floors, Petitioners assert that EPA was not, in fact, required to follow this Court’s decisions mandating this requirement, because those decisions were issued

after 1997 and because they did not specifically overrule Sierra Club-HMIWI. Pet. Br. 21-22.

This Court already has made it abundantly clear that in issuing revised MACT standards pursuant to remand, EPA may not ignore this Court's intervening holdings:

If the Environmental Protection Agency disagrees with the Clean Air Act's requirements for setting emissions standards, it should take its concerns to Congress. If EPA disagrees with this court's interpretation of the Clean Air Act, it should seek rehearing en banc or file a petition for a writ of certiorari. In the meantime, it must obey the Clean Air Act as written by Congress and interpreted by this court.

Sierra Club-Brick, 479 F.3d at 884.³

Of course, these cases merely explain what is required by the statute. CAA §129(a)(3) requires EPA to set the MACT emissions standards based on “*methods and technologies for removal or destruction of pollutants before, during, or after combustion....*” 42 U.S.C. §7429(a)(3) (emphasis added). While control technologies (e.g., scrubbers) generally *destroy* pollutants *during and after* combustion, waste segregation is a *method* (as opposed to a technology) that *removes* pollutants *before* combustion. Therefore, if the state regulatory surrogate does not reflect emissions limitations achieved in part through waste segregation

³ Not surprisingly, Petitioners rely on post-1997 cases when they believe some statement in the court's opinions supports *their* position with regard to how MACT floors are to be applied. See, e.g., Pet. Br. 22-23, 39.

and other non-technology methods, it does not comply with the requirements of CAA §129.

As EPA found on remand, the state regulatory surrogate it utilized for medical incinerators does not, in fact, reflect the use of non-control technology factors. 74 Fed. Reg. at 51,378/2-3. This was established not only by the data of actual emissions, *id.*, but also is evidenced by an examination of the state regulations and permits upon which the 1997 standard was based.⁴

This Court's opinions forewarn that unless EPA can *demonstrate* that factors other than technological controls (e.g., waste segregation and combustion controls) have only a *negligible* effect on emissions, EPA *must* consider them in setting MACT floors. Cement Kiln, 255 F.3d at 866; Sierra Club-Brick, 479 F.3d at 882-83. As EPA explained, "based on recently obtained information, we now understand that factors other than the controls (e.g., waste mix and combustion conditions) affect HMIWI performance, and those emission reduction strategies must be accounted for in MACT floor determinations." 73 Fed. Reg. at 72,975.

This new information included results of a survey that EPA conducted of various medical incinerators. EPA gathered information from nine companies

⁴ See, e.g., JA580-90 (A-91-61, II-B-94 at 3390) (Kansas permit setting requirements based on "best available demonstrated technology," which the permit defined as good combustion and fabric filter for the medical incinerators, i.e., waste segregation was not a basis for the permit requirements).

comprising eighteen units (32% of the existing units), specifically chosen to represent various types of sources (hospitals, pharmaceutical operations, universities, and commercial operations), incinerator sizes, incinerator ages, and control techniques. Id. The survey revealed that waste segregation was a common practice at the six hospitals, the pharmaceutical company, and the university, and that the segregation covered various types of hazardous materials. The commercial incinerator also reported that it encouraged waste segregation from its customers through waste management plans, waste acceptance protocols, and even contract requirements. Id.; JA 645-49 (EPA-HQ-OAR-2006-0534-0316).

Petitioners assert that EPA may not rely on the survey of 32% of the operating medical incinerators, contending that the data cited amount to just a “bald assertion that waste segregation is ‘representative’ of the source category as a whole....” Pet. Br. 24. Yet, Petitioners point to nothing in the record to refute EPA’s conclusions or that otherwise might lead to a conclusion that the effects of waste segregation and other non-control factors utilized by medical incinerators is “negligible,” as required for EPA to ignore such factors. Moreover, actual emissions data revealed that various facilities had to be using waste segregation or other non-control factors because their emissions limitations were significantly below those that could be achieved with just control technologies. 74 Fed. Reg. at 51,378/2-3; JA 729, 737, 745 (EPA-HQ-OAR-2006-0534-0318 at Table 3, lines

356-57 on pp. 346, 354, 362, showing extremely low metals and dioxin/furan emissions from hospitals, despite no pollution control devices).

3. Petitioners Offer No New Explanation Supporting Continued Use of the 1997 State Regulatory Surrogate

As noted, Petitioners cite to no undiscovered 1997 data and no new explanation of the information available in 1997 that could address the defects in the state regulatory surrogate identified by the Court in Sierra Club-HMIWI. Instead, Petitioners rely on supposition about a post-1997 phenomenon (which, under their own theory rejecting all post-1997 data or events, the Court should not even consider) to support their view that the 1997 regulation did, in fact, accurately reflect actual emissions limitations. Noting that “almost 98% of the then-existing facilities [chose] to shut down in response to the 1997 rule,” Petitioners contend that the fact that “only 2% of existing units could comply with the 1997 standards ... unambiguously demonstrates that the 1997 standards were set at least as stringent as the level reflected by the ‘average emission limitation achieved by the best performing 12 percent of units.’ 42 U.S.C. §7429(a)(2).” Pet. Br. 18. Petitioners’ conclusion is, however, pure conjecture.

Prior to 1997, there was no regulation of medical incinerators, and so vast numbers of these units lacked pollution control technology. JA 591-626 (A-91-61, IV-B-45, showing that 75% of medical incinerators had APCD 1-3, i.e., only combustion controls). Any set of standards, therefore, even those based on the

state regulatory surrogate, would require substantial investments in control equipment or other significant actions by these previously uncontrolled sources. Indeed, EPA's analysis showed that "even in the absence of increased regulatory requirements, less expensive alternative waste disposal options are available for almost all facilities that operate HMIWI." 74 Fed. Reg. at 51,396. Thus, EPA predicted in 1997 that most units would cease operations in response to the 1997 Regulation rather than subject themselves to *any* regulation. 62 Fed. Reg. at 48,372/3. Not surprisingly then, Petitioners cite no evidence to refute EPA's equally plausible conclusion that most, if not virtually all, of these 98% of covered medical facilities simply decided that it was prudent to either autoclave and landfill their waste or send it to commercial or other incinerators, rather than continue to operate their own incinerators under *any* emissions standards, even ones eventually determined to be set at levels well above the emissions limitations actually being achieved by the best performing sources.

**4. The Resetting of the MACT Floors Was Consistent
With Congressional Intent**

Notwithstanding the clear Congressional mandate that EPA establish the MACT floors based on the emission limitations actually achieved by the best performing sources, Petitioners assert that EPA's promulgation of the Challenged Regulation -- which does just that -- conflicts with Congressional intent. Citing unrelated statements that Congress did not want EPA to use other subsections of

the CAA, such as the five-year review provision, to impose an “inexorable downward ratcheting effect” of emission standards, Petitioners coin the term “MACT-on-MACT” to give the false impression that EPA’s resetting of the MACT floors pursuant to CAA §129(a)(2) somehow requires sources to constantly upgrade their control technologies. Pet. Br. 26.

First, Petitioners’ MACT-on-MACT label is based on the faulty premise that the original MACT floors accurately reflected what the statute required. Although medical incinerators had to comply with the 1997 MACT floors, the standards were, as it turns out, well above the limitations actually being achieved by some sources and, therefore, well above the limitations required under section 129. Accordingly, a more accurate label for the MACT standards as EPA reset them in 2009 might be: “MACT-on-Unsupportable-Standards-Erroneously-Labeled-as-MACT.”

More to the point, as Petitioners themselves explain, Congress’s concern with an inexorable ratcheting down of the standards was expressed with regard to the five-year technology-based reviews to be conducted under CAA §129(a)(5), which itself presumes the prior issuance of supportable MACT floors. Pet. Br. 26. Although EPA originally proposed revising some emissions standards pursuant to its five-year review, *no* changes were made pursuant to that review provision in the final Challenged Regulation. See p. 21, supra. As EPA explained, because the

MACT floors established in the final rule are “more stringent than what we proposed in 2007 for both the remand response and the 5-year review,” there was no need to further tighten standards pursuant to the Section 129(a)(5) review. 74 Fed. Reg. at 51,372/1.

In any event, Petitioners themselves provide ample evidence that their claim -- that it is unfair to set emissions standards based on the performance of facilities which installed costly control equipment in response to the 1997 regulations -- lacks factual support. For example, if the 1997 emissions standards actually reflected the average actual emissions of the best-performing 12% of units, as Petitioners continue to insist is the case, that would mean approximately 6% of the 2,373 existing units at the time (142 units) were achieving MACT limitations *before* the 1997 standards became applicable. As Petitioners explain, most sources shuttered their incinerators rather than implement mechanisms required to meet these 1997 standards, leaving only 52 existing units operating once the regulations were implemented in 2002. Pet. Br. 9. Since the 52 remaining units would not have to add any control technologies according to Petitioners’ logic, because they presumably were a subset of the 142 units already meeting MACT limitations, the 2009 reset regulations *could not* have unfairly reflected control technologies that existing entities implemented only in order to comply with the 1997 Regulation. Indeed, of the 42 units for which EPA has applicable inventories for both 1995 and

2009, at least two-thirds had the *same* pollution control equipment in 2009 that they had in 1995.⁵

In further support of their claim of unfairness, Petitioners submitted with their comments on the Challenged Regulation a chart showing the differences between some of the 1997 standards and the 2009 reset standards based on actual emissions data, and described the reset standards as requiring changes by “orders of magnitude.” JA 804-05 (EPA-HQ-OAR-2006-0534-0356.1 at 21-22). In fact, what this chart exhibits is how inaccurate the 1997 standards were, in terms of reflecting actual MACT performance limitations. If one assumes that the 52 units which remained in operation after 1997 took little or no action to implement new controls because they already complied with the 1997 standards, and the new regulations are based on the actual emissions of those same 52 units (plus five new ones which began operations after 1997), then Petitioners’ chart starkly exhibits that the 1997 standards were set well above the emissions limitations *actually being achieved* by units operating at the time.

⁵ Utilizing charts compiled by EPA, one can compare the control equipment of a source in 1995 with the control equipment it used in 2009. For example, Merck & Co. utilized a dry injection fabric filter (DIFF) in 1995 (JA 568-69) (A-91-61, II-B-94 at 218-228) and continued to rely on DIFF control to meet the 1997 standards, without installing further controls, in 2009. (JA 1233) (EPA-HQ-OAR-2006-0534-0389 at Appx. A, p. 17).

B. Petitioners' Alternative Arguments Lack Merit

The preambles to the Re-Proposal and the Challenged Regulation include extensive explanation of why and on what bases EPA reset the MACT floors in response to this Court's remand. Nevertheless, Petitioners contend that "EPA does not explain its reversal from the 2007 proposal ..." and that this violates an agency's obligation to explain changes it makes in its regulations. Pet Br. 19. Putting aside the issue of whether an agency is even obligated to provide an explanation for replacing one proposal with another proposal that provides for its own full comment period, EPA explained at great length its reasons for ultimately abandoning the 2007 Proposal. See, e.g., 73 Fed. Reg. at 72,968-70 (labeled "What was EPA's methodology in the 2007 proposed remand response?") and 73 Fed. Reg. at 72,970 (labeled "Why is EPA re-proposing a response to the remand?").

Petitioners next complain that EPA should not be able to rely on data reflecting actual emissions because those data only became available as a result of its delay in responding to the remand in Sierra Club-HMIWI. Pet. Br. 19-20. In the absence of a statutory deadline, an agency's timetable for performing its duties is due "considerable deference," Cobell v. Norton, 240 F.3d 1081, 1096 (D.C. Cir. 2001) (quoting Sierra Club v. Gorsuch, 715 F.2d 653, 658 (D.C. Cir. 1983)), and cannot form the basis for overturning a rule when the agency finally does act.

United Steelworkers of Am., AFL-CIO-CLC v. Rubber Mfrs. Ass'n, 783 F.2d 1117, 1120 (D.C. Cir. 1986).

There exist potential remedies where a party believes an agency is not responding to a remand promptly enough. See NRDC v. EPA, 489 F.3d 1364, 1375 (D.C. Cir. 2007) (declining to set a timetable for EPA to set new emissions standards on remand because “mandamus affords a remedy for undue delay”). Even if, however, Petitioners had successfully prosecuted such an action, the appropriate remedy would have been to compel EPA to promulgate its new rulemaking, not to reach back to unsupportable facts as a basis for its conclusions. Telecomm. Research & Action Ctr. v. FCC, 750 F.2d 70, 81 (D.C. Cir. 1984). Of course, here Petitioners had no incentive to encourage EPA to promulgate revised regulations because it is *Petitioners* who have benefitted from EPA’s delay, by having for the last thirteen years to adhere to emissions limitations considerably less restrictive than the limitations required by the statute.

Petitioners next argue that because EPA referenced comments to the Proposed Rule as bringing to EPA’s attention some of the flaws in its analysis, the Challenged Regulation is invalid because those comments were not raised within sixty days of the original 1997 Regulation. Pet. Br. 25, relying on 42 U.S.C. §7607(b)(1). EPA revised the 1997 standards pursuant to this Court’s remand of those standards, not pursuant to comments. Moreover, it goes without saying that

an agency is free to consider comments to a new proposed regulation issued in response to a remand. In any event, 42 U.S.C. §7607(b)(1) applies only to the timely filing of petitions for review by would-be petitioners. There is *nothing* in this provision that imposes restrictions on when EPA may revise its regulations or what comments or court decisions it may consider in revising its regulations. Indeed, as outlined supra, an agency may correct, revise or even reverse its regulations at *any* time, so long as it explains why it is doing so.

Finally, Petitioners assert that EPA improperly used the five-year review provision of CAA §129(a)(5) in revising the emissions standards. Petitioners claim this provision may only be used to establish or reset beyond-the-floor standards, which requires analysis of costs and other factors that EPA did not address. Pet. Br. 26-29. Similarly, Petitioners assert that in resetting the MACT floors, EPA failed to perform a residual risk analysis, as required when resetting emissions standards pursuant to CAA § 129(h)(3). Pet. Br. 47.

Petitioners' argument fails because their underlying premise simply is wrong. Contrary to their assertion, EPA did not rely upon *either* CAA §129(a)(5) *or* CAA §129(h)(3) to reset the MACT floors. EPA did not conduct a residual risk review of medical incinerators under CAA §129(h)(3) in the Challenged Rulemaking. 72 Fed. Reg. at 5532/3-33/1. And while EPA determined that the revision of the MACT floors pursuant to the Court's remand satisfied EPA's

obligation to *conduct* a five-year review, no further tightening of emissions standards beyond the re-set floors was promulgated as a result of that review. 74 Fed. Reg. at 51,372/1-2.

III. EPA ACTED REASONABLY IN SETTING THE MACT FLOORS ON A POLLUTANT-BY-POLLUTANT BASIS

As outlined supra, EPA set the pollutant-specific numeric MACT floor standards based on emissions limitations actually achieved by the best-performing units for each of the covered pollutants. According to Petitioners, however, CAA §129 *requires* EPA to set the emission standards based on the best-performing single source (or average of the best 12% for existing sources) for “all” nine pollutants combined, rather than the best-performing source for “each” pollutant. Pet. Br. 32-40.

For example, based on emissions limitations actually achieved by various medical incinerators, in the Challenged Regulation EPA set the following MACT floors for new small units:

<u>Pollutant</u>	<u>Units</u>	<u>Emission Limit</u>
Particulate Matter	Milligrams/cubic meter	66
Carbon Monoxide	Parts per million	20
Dioxins/Furans	Nanograms/cubic meter	16
Hydrogen Chloride	Parts per million	15

Sulfur Dioxide	Parts per million	1.4
Nitrogen Oxides	Parts per million	67
Lead	Milligrams/cubic meter	0.31
Cadmium	Milligrams/cubic meter	0.017
Mercury	Milligrams/cubic meter	0.014

74 Fed. Reg. at 51,415. Under Petitioners' theory, in setting the emission standards "achieved in practice by the best controlled similar unit," 42 U.S.C. §7429(a)(2), EPA is *prohibited* from requiring new medical incinerators to meet these enumerated standards which have, in fact, actually been achieved by various existing units. Instead, Petitioners assert that EPA must identify the single unit that comes closest to the emissions limitations being achieved in aggregate, and then reset the standards at the levels reached by that single unit. Petitioners' interpretation is neither compelled by the statute nor can it even be considered by the Court.

A. Petitioners' Claim is Barred by CAA §307(b)

As Petitioners point out (Pet. Br. 24-25), a ruling issued by EPA under the CAA must be challenged within sixty days of its publication in the Federal Register. 42 U.S.C. §7607(b); Am. Road & Transp. Builders Ass'n v. EPA, 588 F.3d 1109, 1112 (D.C. Cir. 2009), pet. for cert. filed, (U.S. June 3, 2010)(No. 09-1485); Env'tl. Defense v. EPA, 467 F.3d 1329, 1330 (D.C. Cir. 2006). This CAA

sixty-day filing period “is jurisdictional in nature and may not be enlarged or altered by the courts.” Motor & Equip. Mfrs. Ass’n v. Nichols, 142 F.3d 449, 460 (D.C. Cir. 1998) (citation omitted).

As EPA made clear at the time, all MACT standards it established in 1997, including the floors, were set on a pollutant-by-pollutant basis. 62 Fed. Reg. at 48,363-64. Commenters in 1997 questioned EPA’s authority to establish MACT standards on a pollutant-by-pollutant basis, and EPA responded by setting forth its reasoning for adopting such an approach. Id. Although a Petition for Review was filed challenging the 1997 Regulation (resulting in the Sierra Club-HMIWI decision), and industry representatives, including Petitioners in this case, participated in that action, *no one* challenged EPA’s pollutant-by-pollutant approach for medical incinerators.

Petitioners themselves explain that “[t]he current standards are based on EPA’s 1997 floor determination,” and, therefore, legal challenges to standards applied as part of that determination are untimely and thus barred by 42 U.S.C. § 7607(b)(1). Pet. Br. 24-25, citing NRDC v. EPA, 529 F.3d at 1084 for the proposition that “the time period for challenging those standards [relating to MACT floors] has long since passed, 42 U.S.C. §7607(b)(1).” It is undisputed that the reset 2009 MACT standards, although different in numeric value, are based on the identical pollutant-by-pollutant metric that EPA established in 1997 for

medical incinerators. Thus, it is too late for Petitioners to now challenge that approach adopted in 1997.

In an attempt to side-step the fact that EPA always has applied a pollutant-by-pollutant approach under section 129, Petitioners try to alter history. They assert that the 1997 standards were actually based on what EPA thought were *achievable* emissions limitations, not on what had actually been achieved. Pet. Br. 37-40. Petitioners contend that because this Court made clear in Sierra Club-HMIWI that MACT floors must be based on emission limitations *actually* achieved, this invalidates EPA's pollutant-by-pollutant approach. Id.

First, EPA never based the 1997 MACT floors on what was achievable rather than on what was achieved. Because the 1997 Regulation also set beyond-the-floor standards based on emission limitations EPA deemed achievable, Petitioners were able to locate a sentence in the 1997 preamble that used the word “achievable” in conjunction with the pollutant-by-pollutant approach. Id. That same preamble, however, makes it abundantly clear that in setting the MACT *floors*, EPA based those emission standards on the limitations EPA then estimated were *actually achieved* on a *pollutant-by-pollutant* basis. 62 Fed. Reg. at 48,363/3-64/1.

Indeed, Petitioners' entire MACT-on-MACT argument is based on the premise that the 1997 standards accurately reflect emission limitations actually

achieved. If Petitioners' argument is now that the 1997 standards were based on the incorrect standard (on what was achievable rather than what was achieved), then their entire MACT-on-MACT argument falls apart because the 1997 standards which they seek to have this Court reinstate are, by their own admission, illegal.

Petitioners may attempt to assert that EPA's promulgation of revised MACT floor standards "reopens" any challenge to matters decided in the 1997 Regulation, thereby allowing Petitioners to circumvent the time bar of 42 U.S.C. §7607(b)(1). Of course, such an argument would directly contradict Petitioners' own position that §7607(b)(1) bars claims by others challenging standards or matters decided in the 1997 Regulation. Pet. Br. 24-25.

In any event, the question of whether the promulgation of a new regulation reopens an issue previously decided by an agency depends upon the actions and announced intentions of the agency. If the agency consciously acts to "reexamine the policy at issue in the petition," that matter may be reopened. Nat'l Mining Ass'n v. Dep't of Interior, 70 F.3d 1345, 1351 (D.C. Cir. 1995). If, however, the agency does not seek comment on the established policy or otherwise affirmatively reconsider it, challenges to the original standard remain barred. Am. Road & Transp., 588 F.3d at 1115; Env'tl. Defense v. EPA, 467 F.3d at 1333; Kennecott Utah Copper Corp. v. Dep't. of Interior, 88 F.3d 1191, 1213 (D.C. Cir. 1996) ("Nor does an agency reopen an issue by responding to a comment that addresses a

settled aspect of some matter, even if the agency had solicited comments on unsettled aspects of the same matter.”).

While EPA re-opened, sought comment on, and re-set the MACT floor emissions limitations in the Challenged Regulation, none of the concerns EPA addressed in responding to the remand in Sierra Club-HMIWI related to EPA setting the standards on a pollutant-by-pollutant basis. Similarly, EPA never suggested nor implied that the fundamental pollutant-by-pollutant approach it has always undertaken to meet the mandates of section 129 was being revisited.

Petitioners may argue that EPA’s pollutant-by-pollutant approach was nevertheless “constructively” reopened. As explained in Sierra-Club-SSM, “[a] constructive reopening occurs if the revision of accompanying regulations ‘significantly alters the stakes of judicial review’ ... as the result of a change that ‘could have not been reasonably anticipated.’” 551 F.3d at 1025 (quoting Kennecott, 88 F.3d at 1214 and Envtl. Def. v. EPA, 467 F.3d at 1334). Constructive reopener requires that the new standard or regulation affect a “sea change” in the manner in which the regulatory scheme works. NRDC v. EPA, 571 F.3d at 1266.

Here, there was no sea change. The identical pollutant-by-pollutant approach was applied in both 1997 and 2009 and the only thing that changed was the data used to set the floors for each pollutant. Moreover, it hardly can be said that the 2009 Challenged Regulation significantly altered the stakes for Petitioners.

It is Petitioners themselves who assert that it was the 1997 Regulation, with its pollutant-by-pollutant approach, that forced the closure of 98% of the 2,400 existing medical incinerators and “resulted in almost a complete shutdown of the medical incinerators industry.” Pet. Br. 3. Thus, Petitioners had more than enough incentive to challenge the pollutant-by-pollutant standard at that time, rather than participate in Sierra Club-HMIWI without raising that issue. Accordingly, this Court is without jurisdiction to address Petitioners’ belated challenge to EPA’s use of the pollutant-by-pollutant metric.

B. In Establishing MACT Floors on a Pollutant-by-Pollutant Basis, EPA Rationally Interpreted its Mandate Under CAA §129

Even if the Court has jurisdiction to address Petitioners’ claim, EPA’s pollutant-by-pollutant approach must be upheld. EPA previously has explained that CAA §129 does not unambiguously declare that MACT floors must be established on a pollutant-by-pollutant basis. 62 Fed. Reg. at 48,363-64. Nevertheless, applying the requirement to set MACT floors based on what has been achieved by the best-performing sources for *each* of the pollutants covered by Section 129, certainly is a rational interpretation of EPA’s obligation under that provision.

Petitioners’ argument is premised on reading in isolation a single clause of a single sentence in the statute. Petitioners cite CAA §129(a)(2), which directs EPA to set MACT floors based on emissions limitations achieved “by the best

controlled similar unit.” Petitioners then leap to the assumption that the “similar unit” *must* be the best-performing source with respect to the entire suite of pollutants. Pet. Br. 32-35.

EPA makes no such leap, since it leads to the illogical result of basing emissions limitations on a source that is not the best-performing source for *any* single covered pollutant. Instead, EPA interprets the provision to require it to establish emissions standards based on the actual emissions of “the best controlled similar unit” for each covered pollutant. 74 Fed. Reg. at 51,380-82. Whichever interpretation is followed, it is clear that mere reference to the statutory requirement that EPA base its standards on emissions levels achieved by “a similar unit” fails to reveal Congressional intent compelling Petitioners’ single-unit theory, since the same reference equally supports EPA’s pollutant-by-pollutant approach.

Amici seize on another isolated clause, asserting that because Congress granted EPA authority to distinguish among classes, types and sizes of units, “distinguishing units by individual pollutant exceeds this limited authority.” Intervenor/Amici Br. 23. But that statutory language regards EPA’s authority to subcategorize sources before setting standards, a step which EPA already took for medical incinerators when distinguishing between large, medium and small units. Within these subcategories EPA is not distinguishing units based on the pollutants they emit; it is setting emissions standards based on pollutant limitations achieved

by units in each subcategory, and is doing so for *all* covered pollutants to be met by *all* operating units.

Petitioners' and Amici's attempts to expand single clauses of the statute beyond their normal meanings simply ignore the rest of the statute in which these clauses appear. Section 129(a)(1) requires EPA to "establish performance standards and other requirements pursuant to section 7411 of this title and this section for each category of solid waste incineration units." Pursuant to CAA §129(a)(2), those standards "shall reflect the *maximum degree of reduction* in emissions of air pollutants listed under section (a)(4)...." (emphasis added). Subsection (a)(4) then states: "The performance standards promulgated under section 7411 of this title and this section and applicable to solid waste incineration units shall specify numerical emissions limitations for the following substances or mixtures: particulate matter (total and fine), opacity (as appropriate), sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins and dibenzofurans." Thus, the statute requires EPA to set individual numeric (a) performance standards; (b) based on the maximum degree of reduction in emissions actually achieved; (c) for each of nine listed pollutants.

Looking at the statute as a whole, EPA declared in 1997: "The EPA does not agree that the MACT floors are to be based upon one overall unit." 62 Fed. Reg. at 48,364. Pointing for instance to subsection 129(a)(4), EPA explained:

This provision certainly appears to direct maximum reduction of each specified pollutant. Moreover, although the provisions do not state whether there is to be a separate floor for each pollutant, the fact that Congress singled out these pollutants suggests that the floor level of control need not be limited by the performance of devices that only control some of these pollutants well.

Id.

Since 1997, the courts have consistently repeated that EPA must set emission standards based on the best-performing source for *each* pollutant. See, e.g., Cement Kiln, 255 F.3d at 858 (“[T]he Agency first sets emission floors for each pollutant and source category....”). Accordingly, EPA’s pollutant-by-pollutant approach has, as outlined above, been in place since 1997 for medical incinerators, and even earlier for other types of incinerators. See, e.g., 59 Fed. Reg. 48,198, (Sept. 20, 1994) (municipal waste combustors). Yet, Petitioners fail to cite to a single case even questioning EPA’s pollutant-by-pollutant approach. Such an approach has, in fact, been upheld in other contexts. See, e.g., Chemical Mfrs. Ass’n v. EPA, 870 F.2d 177, 239 (5th Cir. 1989) (concluding that basing Clean Water Act best available technology standards on a pollutant-by-pollutant basis was a rational interpretation of EPA’s obligations under that similar statute).

Indeed, utilizing the single-unit theory proffered by Petitioners would result in EPA setting the standards at levels that would, for some pollutants, actually be based on emissions limitations achieved by the *worst*-performing unit, rather than the *best*-performing unit, as required by the statute. Petitioners concede that “the

best performers for some pollutants are the worst performers for others.” Pet. Br. 34. See also Pet. Br. 40 (“Some of the best performers for certain pollutants are among the worst performers for others.”) In fact, utilizing Petitioners’ single-unit approach would result in emissions standards for some of the covered pollutants being set at levels well *above* those established even in the 1997 Regulation that Petitioners support. 74 Fed. Reg. at 51,382.

Moreover, a single-unit approach would require EPA to make value judgments as to which pollutant reductions are most critical in working to identify the single unit that reduces emissions of the nine pollutants on an overall best-performing basis. 74 Fed. Reg. at 51,382/2. As EPA explained, such value judgments are antithetical to the command of the statute at the MACT floor stage. Id. It would essentially require EPA to prioritize the nine pollutants based on the relative risk to human health of each pollutant, a criterion that has no place in the establishment of MACT floors. Sierra Club-Copper, 353 F.3d at 979-80.

Amici argue that the single-unit approach would not result in a “least common denominator” standard as EPA has described, because under CAA §129(a)(2) EPA may impose the more stringent beyond-the-floor standards or it may utilize other provisions to impose more stringent risk-based standards. Intervenor/Amici Br. 24-26. The fact that EPA has options to pursue more stringent standards based on what is “achievable” or based on health risks, after

considering costs and other factors, is irrelevant to how EPA is required to set MACT floors. MACT floors must be based on emissions limitations that already have been achieved, without regard to risk, cost and the other factors that are part of more stringent non-floor standards. Nat'l Lime Ass'n, 233 F.3d at 640.

Finally, Petitioners' concerns about the pollutant-by-pollutant approach are overstated. In response to comments on the Challenged Regulation, EPA explained that for some subcategories of medical incinerators, there already exist single units that meet all nine of the new MACT floor emission standards in their subcategory. 74 Fed. Reg. at 51,380/3. Petitioners complain that the single units EPA identified do not meet the revised standards for a *new* unit but instead only meet all nine new standards established for existing sources. Pet. Br. 35. Petitioners also protest that while there admittedly are single units that meet the revised standards for all nine pollutants in the small and large categories, there is no single unit that meets all nine emission standards for medium size medical incinerators. Id. at 35-37. Petitioners appear to imply that EPA's discussion of the ability of certain single units to meet the floors for all nine covered pollutants is an indicator that EPA utilizes a single-unit approach. Id.

Petitioners miss (or misstate) the point. EPA has *never* taken the position that it must identify a single unit that meets the revised standards for all pollutants. Instead, EPA referenced these units for several reasons. First, the identification of

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single units that already meet the revised standards for *each* of the nine pollutants evidences that it is not likely to be overly onerous for sources to meet all required standards, since some already do. Second, EPA was responding to assertions in the comments that certain controls or mechanisms that are designed to reduce emissions of some of the nine covered pollutants might actually increase emissions of other pollutants, i.e., that it might be impossible for a single unit to meet the standards for all nine pollutants. Intervenor/Amici Br. 28. EPA determined that the control techniques required to meet the MACT floors are compatible and that there “do not appear to be any conflicts where meeting the standard for one pollutant may jeopardize the achievability of meeting another pollutant’s limit.” 74 Fed. Reg. at 51,380/3. Petitioners do not challenge this technical finding, nor has this Court endorsed the notion that a MACT floor must be achievable based on a source’s current technology – in fact, it has rejected that premise. NRDC v. EPA, 489 F.3d at 1376.

EPA’s interpretation of whether or not to establish the MACT floor standards on a pollutant-by-pollutant basis must be accorded “an extreme degree of deference,” Huls Am. Inc., 83 F.3d at 452, and must be upheld so long as it is one of any number of rational interpretations. Chemical Mfrs., 470 U.S. at 125. Because there is nothing in the statute that requires EPA to set a standard for a single unit that merely comes as close as possible to reaching the maximum degree

of reduction for all nine pollutants actually being achieved by separate medical incinerators, EPA's pollutant-by-pollutant interpretation must be upheld.⁶

IV. **THE RESET MACT FLOORS ACCOUNT FOR EMISSIONS VARIABILITY**

As authorized by this Circuit's prior rulings, see, e.g., Mossville Environmental Action Now v. EPA, 370 F.3d 1232, 1242 (D.C. Cir. 2004), EPA accounted for emissions variability in resetting the MACT floors for medical incinerators with data showing the connection between the reset MACT floors and the performance achieved over time by the best performing units. As EPA explained, this process allowed EPA to consider emissions limitations achieved in the "worst foreseeable circumstances" by using statistical adjustments to account for emissions variability. 74 Fed. Reg. at 51,381-88. EPA took several steps to account for variability, including: (1) obtaining additional emissions test data representing all available annual test results for each unit; (2) using individual test run data for the best-performing 12 percent of sources to calculate upper confidence values; (3) using a substantial confidence interval (specifically, a 99

⁶ Amici express concern over the *hypothetical* situation of what might happen if the pollutant-by-pollutant standard were applied to the over 100 hazardous air pollutants covered under CAA §112. Intervenor/Amici Br. 28-29. Standards established for other industries, as well as standards established pursuant to CAA §112, are not at issue in this case nor will such hypothetical standards be governed by this case. See Sierra Club-Copper, 353 F.3d at 986.

percent upper confidence level value); and (4) closely reviewing how the data are distributed (e.g., normally, lognormally). Id. at 51,382-83.

Petitioners nevertheless assert that EPA failed to set the MACT floors based on the emissions limitations achieved by the best-performing units operating in the “worst reasonably foreseeable circumstances.” They contend that if a source ever exceeded the MACT floor in any single test, the floor established by EPA cannot possibly have been achieved under the worst foreseeable circumstances. Pet. Br. 41. In other words, Petitioners claim that the worst foreseeable circumstances must always be those reflected in the single test resulting in the highest level of emissions. Pet. Br. 41-43.

A single test simply does not necessarily reflect the actual emissions limitations achieved by the tested unit. As EPA explained, “variations in emissions [test results] may be caused by different settings for emissions testing equipment, different field teams conducting the testing, differences in sample handling, or different laboratories analyzing the results.” 74 Fed. Reg. at 51,387. Cf. Portland Cement Ass’n v. Ruckelshaus, 486 F.2d 375, 396 (D.C. Cir. 1973) (favorably citing the industry’s position that EPA’s emission standards should not be based on a single test). Thus, in response to comments, EPA estimated the “skewness” of data and characterized data distributions as either normal or lognormal prior to calculating upper confidence level values and identifying MACT floor standards

that account for variability. 74 Fed. Reg. at 51,387. Petitioners do not challenge EPA's use of this data distribution and statistical methodology for addressing variability or that it was a reasonable approach to account for reasonably foreseeable adverse circumstances.

Petitioners further assert that because the 2009 emissions standards do not exempt emissions that may occur during malfunctions, those standards cannot possibly reflect emissions during the "worst reasonably foreseeable circumstances." Pet Br. 43-46. This argument, which is based on the elimination of the exemption from emissions standards during malfunctions, is barred because it was not raised in comments or in a petition for reconsideration to the Agency. See pp. 67-70, infra. Even if the Court did have jurisdiction to address this argument, however, it is wholly without merit.

First, it is obviously impossible to anticipate what malfunctions are going to occur in every covered unit, how long they will last, and what effect, if any, such malfunctions will have on emissions. Moreover, EPA explained that "[i]t would be very difficult to do any meaningful testing during such an event because the exhaust flow rates, temperatures, and other stack conditions would be highly variable and could foul up the isokinetic emissions test methods (thus invalidating the testing)." 74 Fed. Reg. at 51,394.

Under Petitioners' reasoning, EPA would have to base its emissions limitations that are required to reflect the *lowest* emissions limitations actually achieved, on units operating under the worst malfunction conditions, i.e., where all pollution controls have broken down and remain unrepaired. This would perversely result in MACT floors based on the *highest* emissions levels possible. This Court has said numerous times that EPA cannot use the variability of emissions to apply methodologies that will result in standards based on the worst-performing units. Sierra Club-Brick, 479 F.3d at 882; Cement Kiln, 255 F.3d at 865.

Given the extreme deference accorded to EPA on technical matters such as these, American Farm Bureau Federation, 559 F.3d at 519, EPA's determination -- that its analysis of testing and accounting for variability of circumstances under which medical incinerators operate, adequately adjusts the emissions standards to reflect the worst reasonably foreseeable circumstances -- must be upheld.

V. EPA ACTED REASONABLY IN ELIMINATING THE EXEMPTION FOR STARTUP, SHUTDOWN AND MALFUNCTIONS

As EPA fully detailed, exemption for emissions occurring during SSM events was not only legally questionable in light of the recent decisions of this Court, its continued application to medical incinerators simply was not justified based on the facts. 74 Fed. Reg. at 51,394. Under the 1997 Regulation, EPA

excused exceedances of emission standards during SSM events, but only in instances where no waste was charged to the incinerator. 40 C.F.R. §60.56c(a) (1998). If waste was still being charged to the incinerator during these events, any emissions that occurred were still counted in assessing compliance with the MACT emissions standards. In the Challenged Regulation, EPA removed the exemption for SSM events because EPA determined that it had virtually no utility for medical incinerators. 74 Fed. Reg. at 51,394.

Petitioners contend that EPA's removal of the SSM exemption cannot be upheld because: (a) EPA failed to provide notice in its Re-proposed rulemaking that it was intending to eliminate the SSM exemption and; (b) EPA's finding that the *malfunction* portion of the SSM exemption is of virtually no utility, is not supported by the record. Pet. Br. 46-53. In fact, it is Petitioners' arguments that are both procedurally defective and lacking any support in the record.

**A. CAA §307(d)(7)(B) Bars Petitioners' Claim Challenging
Elimination of the SSM Exemption**

Under CAA §307, "[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review." 42 U.S.C.

§7607(d)(7)(B); Mossville Env'tl. Action, 370 F.3d at 1238. "Petitioners who fail to comply with this exhaustion requirement are barred from seeking judicial

review.” Nat’l Ass’n of Clean Air Agencies v. EPA, 489 F.3d 1221, 1231 (D.C. Cir. 2007).

Although elimination of the SSM exemption was not expressly proposed in the Re-proposal, Petitioners were nevertheless required to raise any objections on that issue through an administrative petition for reconsideration submitted directly to EPA before seeking judicial review. 42 U.S.C. §7607(d)(7)(B); Nat’l Ass’n of Clean Air Agencies, 489 F.3d at 1232 (“[E]ven where the ground for an objection arose after the period for public comment..., the petitioner must first seek a proceeding for reconsideration. Only then may petitioner seek judicial review.”) (quoting Appalachian, Power Co. v. EPA, 249 F.3d 1032, 1055 (D.C. Cir. 2002)); Texas Mun. Power Agency v. EPA, 89 F.3d 858, 875-76 (D.C. Cir. 1996). Because Petitioners filed no such petition for reconsideration (see Dkt. 1224190, Line 6d), the Court lacks jurisdiction to address the SSM issue. 42 U.S.C. §7607(d)(9)(D) (“In the case of review of any action of the Administrator to which this subsection applies, the court may reverse any such action found to be--(D) without observance of procedure required by law, *if* ... (ii) the requirement of paragraph (7)(B) has been met....”) (emphasis added).

Even *if* Petitioners had filed a petition for administrative reconsideration as required, the Court would still not have a basis to grant relief. CAA §307(d)(8) declares that with regard to alleged procedural errors, such as lack of notice of

EPA's intent to modify an existing rule, "the court may invalidate the rule *only* if the errors were so serious and related to matters of such central relevance to the rule that there is a *substantial likelihood* that the rule would have been significantly changed if such errors had not been made." 42 U.S.C. §§7607(d)(8) (emphasis added). See also §7607(d)(9)(D)(iii). There is no such likelihood here.

First, as detailed infra, Petitioners cite to no evidence that EPA's conclusion that the SSM exemption is virtually useless for medical incinerators is incorrect, let alone evidence that results in a substantial likelihood that EPA would reinstate the exemption. Additionally, in Sierra Club-SSM, this Court vacated a similar, albeit less limited, SSM exemption that EPA has often incorporated into MACT standards issued under CAA §112. 551 F.3d at 1026-28. Contrary to Petitioners' assertion that the Court's holding was based on provisions unique to Section 112, the Court's analysis suggests otherwise. The Court found that the definition of "emission standards," which appears at 42 U.S.C. §7602(k), and which applies equally to sections 112 and 129, requires EPA to apply MACT emissions standards on a continuous basis, thereby precluding exemptions applied for malfunctions or other singular events. 551 F.3d at 1027.

Although EPA did not affirmatively base its revocation of the SSM exemption applicable to medical incinerators on the Court's decision in Sierra Club-SSM, it concluded that in light of that case the continued legal viability of the

SSM exemption for medical incinerators is in doubt. 74 Fed. Reg. at 51,394/2.

This ruling must, therefore, be considered (assuming the Court concludes it has jurisdiction over this issue) in determining whether there is a substantial likelihood that EPA would reinstate the SSM exemption on remand, as is required to uphold Petitioners' procedural argument under CAA §307.

B. EPA's Decision to Eliminate the SSM Exemption is Supported by the Administrative Record

As outlined supra, an agency is free to change or even reverse its position in an earlier regulation, so long as it provides an explanation for the change. EPA's obligation to explain the bases for its policies or interpretations "is not particularly demanding." Biovail Corp. v. U.S. Food & Drug Admin., 519 F. Supp. 2d 39, 45 (D.D.C. 2007). Nothing more than a brief statement is necessary, as long as the agency explains its actions. Tourus Records, Inc. v. DEA, 259 F.3d 731, 737 (D.C. Cir. 2001). This standard is no different when an agency changes or reverses a prior policy. FCC v. Fox Television, 129 S. Ct. at 1811.

Petitioners concede that EPA had a substantive basis to remove the exemption for medical incinerators for start-up and shut-down. Pet. Br. 50. As to malfunctions, EPA detailed precisely why it believed that a continued exemption was unnecessary, even if there might be some residual waste to be burned after a malfunction occurred:

Malfunctions present a similar situation [to startups and shut downs] in terms of how the 1997 rule functioned, if a slightly different situation factually. Again, the SSM exemption of [40 C.F.R.] §60.56c(a) applied only where no hospital waste and no medical/infectious waste was being charged [to the incinerator]. Under §§60.56c(a) and 60.37e(a) of the HMIWI rules, facilities are required to stop charging waste as soon as a malfunction is identified and not charge any additional waste.... During malfunction periods, operators must operate within established parameters as much as possible and continue to monitor all applicable operating parameters. So, there should be low emissions during such periods, but how low is not known.

74 Fed. Reg. at 51,394/3. See also id. at 51,393-95.

Petitioners contend that “EPA provides no support for its claim that the *malfunction* exemption was of ‘virtually no utility.’” Pet Br. 50. Petitioners assert that although EPA correctly states that there should be low emissions during malfunction periods because, by definition, no waste can be charged to the system during malfunction periods, the small amount of waste to be combusted that may remain in the unit warrants continued application of the SSM exemption during malfunctions. Pet. Br. 51.

Yet, Petitioners fail to identify any record materials evidencing *any* events where residual waste was incinerated during a malfunction, let alone waste in amounts that would warrant an exemption, assuming arguendo that such an exemption would survive legal scrutiny following Sierra Club-SSM. As EPA stated, “our final standards established today are based on the best data available to the Agency, and we have no data to support modifying the floors for malfunction

periods.” 74 Fed. Reg. at 51,394/3. And, as noted, no such data was submitted as part of any petition for reconsideration.

Moreover, EPA provided an alternative process for addressing emission exceedances that might occur during a malfunction event. EPA explained that

[i]n the event that sources, despite their best efforts, fail to comply with applicable standards during SSM events (as defined by the rule), EPA will determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during SSM periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions.

74 Fed. Reg. at 51,394/3-95. While Petitioners may prefer a blanket exemption, it cannot be said that this individualized approach is an unreasonable way to deal with the limited number of instances where a malfunction *may* lead to an emissions exceedance.

Finally, using a partial quote from a Clean Water Act case, Petitioners imply that EPA may not eliminate an exemption “solely on the ground that it would be of little use to dischargers.” Pet. Br. 50 (quoting NRDC v. EPA, 859 F.2d 156, 210 (D.C. Cir. 1988)). That case held that EPA *could*, in fact, eliminate the exemption on just this basis. The Court merely explained that EPA had to provide some explanation as to why the exemption would be of little use, rather than base its conclusion on “mere speculation.” Id.

Agency actions are presumed to be valid, Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir. 1976), and should be upheld so long as the agency considered

relevant factors and articulated a rational connection between the facts found and the choices made. Marsh v. Or. Natural Res. Council, 490 U.S. 360, 378 (1989).

While Petitioners may disagree with EPA's conclusion that the SSM exemption "provided virtually no utility, and we therefore expect that today's deletion of the SSM exemption will have very little, if any, impact on HMIWI units' compliance status," 74 Fed. Reg. at 51,394/3, it cannot be said that EPA failed to articulate a reasoned factual basis for its choice to eliminate the exemption.

Given the lack of data relating to any significant continued combustion of waste after a malfunction event, Petitioners' admission that EPA has "wide latitude in determining the extent of data-gathering necessary to solve a problem," Pet. Br. 8, and EPA's alternative individualized methodology for dealing with emissions that may occur during malfunctions, EPA's conclusion that an continued exemption for malfunction events was unnecessary, must be upheld.

CONCLUSION

For the foregoing reasons, the Petition for Review should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE UNDER FED. R. APP. P. 37(A)(7)(b)

This brief complies with the type-volume limitation of Fed. R. App. P. 32 (a)(7)(B) because this brief contains 15,990 words, excluding the parts of the brief exempt under Fed. R. App. P. 32 (a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typeface style requirements of Fed. R. App. P. 32(a)(6) because the brief was prepared in proportionally spaced typeface using Microsoft Word 14 point Times New Roman type.

So certified this 14th day of September, 2010, by

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing BRIEF OF RESPONDENT ENVIRONMENTAL PROTECTION AGENCY was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of said filing to the attorneys of record for Petitioners and all other parties, who have registered with the Court's CM/ECF system.

Date: September 14, 2010

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